TREATMENT INFORMATION GROUP
thinking about AIDS drugs
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15 September 2005

Lindie Dippenaar
Advertising Standards Authority of South Africa
Willowview Burnside Island Office Park
410 Jan Smuts Avenue
Craighall Park

Per telefax 011 781 1616
And post.

Dear Ms Dippenaar

TREATMENT ACTION CAMPAIGN AND GEORGE STACY / THE DR. RATH HEALTH FOUNDATION AND THE TREATMENT INFORMATION GROUP

1. We'd like some clarity regarding the ASA ruling of 24 August against the Dr. Rath Health Foundation, which purports to limit the ability of the Treatment Information Group (TIG), the Traditional Healers Organization (THO) and the South African National Civics Organization (SANCO) to advertise freely in the media as well, by requiring these organizations to submit to censorship by the ASA in respect of any material they wish to publish in future – the costs of which procedure they are required to pay.

Considering that:

- The TIG is an independent voluntary association;

- The TIG was not a party to the proceedings on 13 July at which sanctions against the Dr. Rath Health Foundation were considered, and on 24 August imposed; and,
- It was never alleged by the TAC that the TIG breached the 9 March ruling:

Does the ASA accept that it erred in unlawfully making a ruling against parties neither accused, nor afforded their basic rights under the *audi alteram partem* rule, before sanctions were imposed on them?

May we treat the erroneous ruling in this regard as *pro non scripto*?

If not, on what legal basis did the ASA purport to limit the TIG's right to express itself in the media in regard to major public health issues, and to require it to pay to be censored first?

We assume it's not merely because the TIG broadly shares the Dr. Rath Health Foundation's public health objectives, and has accordingly formed an alliance to pursue them.

2. Annexed hereto is a list of citations concerning AZT from the medical literature, interspersed with public statements about the drug by *inter alia* President Mbeki, Health Minister Dr Tshabalala-Msimang, GlaxoSmithKline medical director Peter Moore, the TAC's Zackie Achmat and Mark Heywood, Supreme Court of Appeal Judge Edwin Cameron, AZT inventor Professor Richard Beltz and various leading AIDS experts both here and abroad.

Assuming that the TIG is not subject to censorship by the ASA Advisory Service before it publishes any advertising in future, is the TIG nonetheless prohibited by the 9 March ruling from republishing the listed citations and statements?

For instance, is the TIG permitted by the ASA to quote President Mbeki's warning to the people of South Africa in his address to Parliament on 28 October 1999?

> There … exists a large volume of scientific literature alleging that, among other things, the toxicity of this drug [AZT] is such that it is in

> fact a danger to health. These are matters of great concern to the government as it would be irresponsible for us not to heed the dire warnings which medical researchers have been making.

May we quote from President Mbeki's letter to Tony Leon of 1 July 2000?

> In your letter to me of June 19, you make the extraordinary statement that AZT boosts the immune system. Not even the manufacturer of this drug makes this profoundly unscientific claim. The reality is the precise opposite of what you say, this being that AZT is immuno-suppressive. Contrary to the claims you make in promotion of AZT, all responsible medical authorities repeatedly issue serious warnings about the toxicity of antiretroviral drugs, which include AZT.

May we quote from Dr Tshabalala-Msimang's address to Parliament on 16 November 1999?

> AZT is a drug that was developed for use in chemotherapy for cancer patients. It was, however, never used in cancer patients because it was regarded as too toxic to use. Tests have clearly shown that rats that were exposed to high levels of AZT for prolonged periods of time, developed vaginal cancer. This is a very serious finding. Other toxicological data exists with respect to AZT, including damage to nerves, muscles and bone marrow.

Or are President Mbeki and Dr Tshabalala-Msimang's statements hit by the ASA ruling of 9 March? In other words, would the TIG be in breach of the 9 March ruling by republishing their statements in a pamphlet or newspaper article?

If, in the view of the ASA, the TIG *is* subject to the censorship sanction imposed on it by the ASA Advisory Committee, notwithstanding the fact that it was not a party to the proceedings of 13 July and it was not offered an opportunity to oppose it, would the TIG be required to submit President Mbeki and Dr Tshabalala-Msimang's statements to ASA Advisory Committee in order for the Committee to decide whether they were telling the truth or lying before the TIG publishes them again.

Is the TIG permitted to place an advertisement in the media reciting, for instance:

- '[F]or AIDS patients, it is urgently necessary to develop a remedy substituting this toxic substance, AZT.' Hayakawa et al., *Biochemical and Biophysical Research Communications* (1991) 176:87-93
- 'Clinical manifestations of ANA [*antiviral nucleoside analogues, such as AZT*] toxicity: It is self-evident that ANAs, like all drugs, have side-effects. However, the prevalent and at times serious ANA mitochondrial toxic side-effects are particularly broad ranging with respect to their tissue target and mechanisms of toxicity: Haematological; Myopathy; Cardiotoxicity; Hepatic toxicity; Peripheral neuropathy.' Lewis and Dalakas, *Nature Medicine* (1995) 5:417-22
- 'The antiretroviral drugs currently licensed in the United Kingdom are zidovudine (azidothymidine), zalcitabine (ddC) and didanosine (ddI). … All are very toxic. Suppression of bone marrow elements can occur with any of the three, as can peripheral neuropathy.' *Adverse Drug Reaction Bulletin*, No.178, June 1996
- '[AZT-class drugs] are much more toxic than we considered previously. … The layer of fat-storing cells directly beneath the skin, which wastes away … is loaded with mitochondria … other common side effects of [AZT and similar drugs are] nerve and muscle damage, pancreatitis and decreased production of blood cells … all resemble conditions caused by inherited mitochondrial diseases.' Brinkman et al., *Lancet* (1999) 354(9184):1112-5
- '[T]he scientific literature does elucidate … a number of biochemical mechanisms which predicate the likelihood of widespread, serious toxicity from use of this drug. … Based on all these data it is difficult if not impossible to explain why AZT was introduced and still remains the most widely recommended and used anti-HIV drug. [The continued administration of AZT] either alone or in combination … to HIV sero-positive or AIDS patients warrants urgent revision.' Papadopulos-Eleopulos et al., *Current Medical Research and Opinion*, (May 1999)

> Special Supplement 15*: A critical analysis of the pharmacology of AZT and its use in AIDS*

Or would publication of these findings be in breach of the 9 March ruling?

If we may publish some of the statements listed in the annexure, but not others, please indicate by striking out those that would constitute a breach of the 9 March ruling were we to publish them without ASA Advisory Committee approval.

Our question is not academic: We propose publishing the statements listed in annexure in the form of a booklet entitled *Introducing AZT*, and distributing it widely, but we don't want to fall foul of the ASA's 9 March ruling (or its 13 July ruling if it applies to us) in doing so.

3. Apropos of the ASA ruling on 9 March that the TIG publish a corrective advertisement concerning its claims that:

- Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system.
- Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death.

Would it be acceptable to the ASA for the TIG to publish a full-page retraction advertisement in the *Mail&Guardian* in which the statements are repeated for reference, followed by a disavowal along the following lines:

> The Advertising Standards Authority of South Africa has ruled that the above statements are unsubstantiated and must be withdrawn. We withdraw them accordingly. But you judge for yourself:

followed by a selection of substantiating citations from the medical literature, as well as statements both in favour of AZT and adverse to it from the annexed list?

If publication of substantiating scientific findings together with the retraction statement is not acceptable to the ASA, would it be acceptable for the TIG to publish a retraction in the following terms?

> The Advertising Standards Authority of South Africa has ruled that the following statements made by the Treatment Information Group are unsubstantiated and must be withdrawn:
>
> - Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system.
> - Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death.
>
> The Treatment Information Group accordingly withdraws these statements. Hundreds of studies have not found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system. Numerous studies have not found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death.
>
> President Mbeki misinformed Parliament on 28 October 1999 when he stated that:
>
> > There … exists a large volume of scientific literature alleging that, among other things, the toxicity of this drug [AZT] is such that it is in fact a danger to health. These are matters of great concern to the government as it would be irresponsible for us not to heed the dire warnings which medical researchers have been making.

There does not exist a large volume of scientific literature alleging that the toxicity of AZT is such that it is in fact a danger to health.

Glaxo Wellcome (now GlaxoSmithKline) responded truthfully in stating:

> The President has been gravely misinformed about the safety aspects of AZT. … The review ordered by President Mbeki of the anti-AIDS drug is neither necessary nor justified … there is no new data that will raise legitimate concerns about AZT's safety. … GlaxoWellcome are a reputable company. We do not lie to people.

Dr Tshabalala-Msimang misled Parliament in falsely stating on 16 November 1999 that:

> AZT is a drug that was developed for use in chemotherapy for cancer patients. It was, however, never used in cancer patients because it was regarded as too toxic to use. Tests have clearly shown that rats that were exposed to high levels of AZT for prolonged periods of time, developed vaginal cancer. This is a very serious finding. Other toxicological data exists with respect to AZT, including damage to nerves, muscles and bone marrow.

President Mbeki's statements in his letter to Tony Leon of 1 July 2000, published in the *Sunday Times*, were incorrect, misleading and confusing:

> In your letter to me of June 19, you make the extraordinary statement that AZT boosts the immune system. Not even the manufacturer of this drug makes this profoundly unscientific claim. The reality is the precise opposite of what you say,

> this being that AZT is immuno-suppressive. Contrary to the claims you make in promotion of AZT, all responsible medical authorities repeatedly issue serious warnings about the toxicity of antiretroviral drugs, which include AZT.

The French Paediatric HIV Infection Study Group (led by Stéphane Blanche) did not report in *Lancet* (354(9184):1084-9) in September 1999: 'Our findings support the hypothesis of a link between mitochondrial dysfunction [*in babies*] and the perinatal administration of prophylactic nucleoside analogues.' [*Eight children were born with severely impaired energy metabolism and corresponding muscle and other cell damage, manifesting in heart muscle injury and muscle weakness generally. Five children, of whom two died, presented with delayed neurological symptoms – extensive brain damage in the form of massive cortical necrosis, cortical blindness, epilepsy and spastic quadriplegia, and three were described as 'symptom-free' but had 'severe biological or neurological abnormalities'. Four of the children had been exposed in utero to AZT and 3TC combined, and four to AZT alone. None were HIV-positive.*]

The French Paediatric HIV Infection Study Group (led by Béatrice Barret) did not publish confirmatory findings in *AIDS* (17(12): 1769-1785) in August 2003:

> An exhaustive study in a large prospective cohort [of AZT- and 3TC-exposed children found] unexplained symptoms compatible with mitochondrial dysfunction. A total of 2644 of 4392 children were exposed to antiretrovirals … All the children with 'established' or 'possible' mitochondriopathy diagnosed in this study had been exposed to antiretroviral

> drugs … in the pre, per- and post-partum periods. … The finding that the use of antiretroviral nucleoside analogues in the perinatal period is associated with persistent mitochondrial disease is confirmed … a risk about 30 times higher than that in the general population. … Despite active screening, no similar cases were found in the antiretroviral unexposed group. … by age 18 months … a coherent syndrome is appearing with three main features: neurological symptoms (principally developmental retardation, seizures and behavioral disturbances), significant abnormalities on cerebral MRI (principally lesions of the white matter and brainstem) and often hyperlactataemia either persistent or transient outside the treatment period. First described as a myopathy associated with zidovudine, the issue of mitochondrial toxicity of nucleoside analogues is currently a growing problem. Its clinical expression is highly variable, from peripheral neuropathy to severe lactic acidosis.

Nor did the French Paediatric HIV Infection Study Group (led by Marc Tardieu) publish follow-up findings in the *American Journal of Neuroradiology* (26(4):695-701) in April 2005:

> Mitochondrial dysfunction has been reported in HIV-negative children perinatally exposed to zidovudine, a drug often used in HIV-seropositive mothers during pregnancy. The purpose of this study was to determine the incidence of cerebral MR imaging findings in HIV-uninfected children exposed to zidovudine who present with unexplained neurologic symptoms. … Images observed in children with

antiretroviral-induced mitochondrial dysfunction are similar to those observed in congenital mitochondrial diseases.

Or something along those lines? Would that be satisfactory?

4. The ASA has had Professor Sam Mhlongo's Expert Verification Statement before it for several weeks now. Kindly let us know when the ASA will be sitting again to determine the merits of the submissions filed in substantiation of our claims about the dangerous toxicity of AZT and the clinical benefits of micronutrient therapy in AIDS – the claims made in our Public Health Information article in the *Mail&Guardian* on 26 November 2004 that caused all the trouble.

We believe that the ASA ruling of 9 March has created an untenable situation in which information that we published with enormous ramifications for public health in South Africa has been found unsubstantiated by the ASA by default – as if no evidence in support of our claims was submitted, whereas in fact three lever-arch files full of scientific data were. The ASA held that it wanted a single independent credible expert to substantiate the claims; the hundreds of experts cited wouldn't do, and so were simply disregarded.

You will appreciate that this is no ordinary matter, but one of immense and pressing public importance. We accordingly look forward to your detailed advices as a matter of urgency please.

Yours faithfully

ADV ANTHONY BRINK
Convener and National Chairman:
Treatment Information Group
Cc: Dr Tshabala-Msimang, National Minister of Health

Phephsile Maseko, National Coordinator, Traditional Healers Organization